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SECTION 2 – 510(k) SUMMARY

Passing Needle with ETHIBOND, PANACRYL or ORTHOCORD suture; and
Passing Needle with ETHIBOND Loop

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson company 249 Vanderbilt Avenue Norwood, MA 02062
Contact Person	Ruth C. Forstadt Project Management Lead, Regulatory Affairs DePuy Mitek a Johnson & Johnson company 249 Vanderbilt Avenue Norwood, MA 02062 Telephone: 781-251-3188 Facsimile: 781-278-9578 e-mail: rforstad@dpyus.jnj.com
Name of Medical Device	Classification Name: ETHIBOND Non-absorbable poly(ethylene terephthalate) suture under 21 CFR 878.5000. PANACRYL Absorbable surgical suture, polydiaxanone under 21 CFR 878.4493. ORTHOCORD PDS Suture carries an FDA product code NEW, and is classified as absorbable surgical suture, polydiaxanone under 21 CFR 878.4840. Polyethylene sutures carries an FDA product code GAT, and is classified under 21 CFR 878.5000. Common/Usual Name: Suture Proprietary Name: Passing Needle with ETHIBOND, PANACRYL or ORTHOCORD suture; and Passing Needle with ETHIBOND Loop

Substantial Equivalence	PANACRYL sutures have been cleared by FDA - K964345; ETHIBOND sutures have been approved by FDA - NDA 17-804 & 17-809; ORTHOCORD sutures have been cleared by FDA- K040004
Device Classification	Sutures are Class II devices.
Device Description	Mitek Passing Needle with ETHIBOND, PANACRYL or ORTHOCORD suture is a suture and needle assembly to be used *in vivo* for suture passage through soft tissue during the surgical procedure. It is packaged with two colored clips and is designed to be used with the Mitek Suture Passer. The Passing Needle with PANACRYL, ETHIBOND or ORTHOCORD suture may also be used with other Mitek anchor products. Mitek Passing Needle with ETHIBOND Loop is a ***utility*** suture and needle assembly that is used *in vivo* for suture passage of operative suture through soft tissue during the surgical procedure. It is packaged with a colored clip and is designed to be used with the Mitek Suture Passer.
Indications for Use	Passing Needle with PANACRYL, ETHIBOND, or ORTHOCORD suture is indicated for use in general soft tissue approximation and/or ligation in orthopedic procedures. Specifically Arthroscopic Bankart and Rotator Cuff Procedures encompassing tendon and ligament reconstruction. Mitek Passing Needle with ETHIBOND Loop is indicated for use in general soft tissue approximation and/or ligation in orthopedic procedures. Specifically Arthroscopic Bankart and Rotator Cuff Procedures encompassing tendon and ligament reconstruction.
Safety	These sutures have been cleared through K964345 (PANACRYL), NDA 17-804 & 17-809 (ETHIBOND) and K040004 (ORTHOCORD). Safety data may be referenced in these documents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2004

Ms. Ruth C. Forstadt
Project Management Lead, Regulatory Affairs
DePuy Mitek
A Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K041806
Trade/Device Name: Passing Needle with Ethibond, Panacryl or Orthocord suture; and Passing Needle with Ethibond Loop
Regulation Number: 21 CFR 878.4493, 21 CFR 878.4840, 21 CFR 878.5000
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture; Absorbable polydioxanone surgical suture; Nonabsorbable poly(ethylene terephthalate) surgical suture.
Regulatory Class: II
Product Code: GAM, NEW, GAT
Dated: June 30, 2004
Received: July 6, 2004

Dear Ms. Forstadt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041806

Device Name:____Passing Needle with ETHIBOND, PANACRYL or ORTHOCORD suture; and Passing Needle with ETHIBOND Loop

Indications For Use:

Passing Needle with ETHIBOND, PANACRYL or ORTHCORD suture is indicated for use in general soft tissue approximation and/or ligation in orthopedic procedures. Specifically Arthroscopic Bankart and Rotator Cuff Procedures encompassing tendon and ligament reconstruction.

Passing Needle with ETHIBOND Loop is indicated for use in general soft tissue approximation and/or ligation in orthopedic procedures. Specifically Arthroscopic Bankart and Rotator Cuff Procedures encompassing tendon and ligament reconstruction.

Prescription Use ____√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041806